

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed January 9, 2009. Currently, claims 1-3, 5-16, 19, and 20 remain pending. Claims 1-3, 5-16, 19, and 20 have been rejected. The Office Action Summary indicates that the Office Action is both Final and non-final. Private PAIR indicates that the Action is non-final and this Response assumes that PAIR is correct. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-3, 5-16, 19, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (U.S. Patent No. 6,416,522), in view of Hlavka et al. (U.S. Published Patent Application No. 2004/0172046), hereinafter Hlavka, and Moss (U.S. Patent No. 5,085,661). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, nowhere does Strecker appear to disclose “a fixation component slidably disposed in each of the delivery channels, each fixation component having a proximal end formed with a slot, a first fixation member, a second fixation member, and a tether connecting the first and second fixation members”. Furthermore, nowhere does Strecker disclose “each of the delivery members have a longitudinal slot communicating with an exterior of the delivery member and extending a length of the delivery channel, wherein the tether passes through the longitudinal slot of the delivery members”. Additionally, the Examiner has acknowledged these deficiencies of Strecker.

As discussed in the Response of December 22, 2008, neither Strecker nor Hlavka appear to disclose a longitudinal slot designed to receive a tether joining a pair of first and second fixation members, said longitudinal slot communicating with an exterior of the delivery channel, wherein a tether passes through the longitudinal slot of the delivery

members. This feature is greatly advantageous because it allows the movement of the pair of tethered fixation members within the channels of the delivery members. Attention is called to the fact that the operation of the placcation inducing device of Hlavka illustrated in the cited Fig. 10A requires the implantation of two or more spaced-apart T-bar fixation elements (904), two or more pledgets to distribute forces, at least one thread, and at least one locking bar which must be implanted together and adjusted in a multi-step operation whereas the operation of Strecker relies instead on the simple insertion of a single device without the need for auxiliary devices or adjustments. Accordingly, one of ordinary skill in the art would not be motivated to incur the significant additional mechanical and operational complexity in order to obtain a result which Strecker obtains with a single securing means. Were one to replace the fixed length, one piece securing means of Strecker, which attaches two layers of tissue, with the six piece structure of Hlavka, which structure is configured to create a plication within a single layer of tissue, the substitution would appear to impermissibly alter the principle of operation of the device of Strecker. (MPEP 2143.01, VI.)

Note also that the pending claims describe fixation components, each of which comprises three elements: a first fixation member, a second fixation member, and a tether connecting the first and second fixation members and that each three element fixation component is disposed in one of a multiplicity of delivery channels with the tether connecting the first and second fixation members passing through the longitudinal slot of the delivery member for that fixation component. The Examiner has advanced elements 904 and 905 of Hlavka as providing first and second fixation members; however plegets 905 of Hlavka do not appear to provide fixation elements. The plegets are said to be formed from materials including, but “not limited to silk and substantially any biocompatible porous or fibrous material” and serve to “effectively cushion” and prevent T-bars 904 from cutting through the single layer of tissue.

The securing means of Strecker appears to be a one piece article lacking the flexibility introduced by the tether of the pending claims. Hlavka appears to introduce unnecessary mechanical complexity and the apparent need to separately implant multiple T-bars spaced apart by a distance fixed by the operation of the locking bar. Accordingly,

one of ordinary skill in the art would not be motivated to turn to the placcation inducing devices of Hlavka to improve the layer securing means of Strecker.

In an attempt to remedy the acknowledged deficiencies of Strecker in view of Hlavka, the Examiner has advanced Moss as teaching a delivery member **6** comprising a longitudinal slot; however the slot of Moss appears to accept and release a single fastener head **38** attached to a tether **46** which extends from the delivery member **6** to a second fastener head **38'** which does not appear to be contained within delivery member **6**. Accordingly, the slot **42** of Moss does not appear to provide a longitudinal slot extending a length of the delivery channel capable of allowing a tether connecting first and second fixation members to pass therethrough for the simple reason that at no time are the first and second fixation members of the fixation component in question both contained within the delivery member of Moss, said delivery member apparently capable of containing only one fastener head, either **38** or **38'**, but not both at the same time. The Examiner has suggested that the single T-bar slot of Moss, with its most proximal extent lying just proximal of the midpoint tether of a single T-bar, would “allow for the tether fixation devices to be used with a pusher delivery system, presumably that of Strecker or the multi-component device of Hlavka. The Applicants must respectfully disagree. The slotted delivery system of Moss does not appear to be capable of holding and delivering its own tether system of two T-bars, much less the more complex six component placcation inducing devices apparently required by the Examiner’s proposed combination of Strecker and Hlavka. Instead, Moss appears to hold and implant one T-bar at a time with the second T-bar residing outside of the delivery member during the implantation of the first. This appears to require locating and inserting the second T-bar into the cavity of the Moss implantation device and retracting the tip to secure it in position. This would appear to be difficult at best under the conditions encountered in inserting a graft and would also appear to require a much longer tether, such as the slack tether employed Moss, than would be functional in securing a graft to a vessel wall. Thus one of ordinary skill in the art would not be motivated to make the combination for the reasons previously advanced and for at least the reason that Strecker already delivers a less complex securing means and does so with a pusher delivery system which does not require the slotted structure of Moss or an undesirably long tether. There appears to be

no motivation for one of ordinary skill in the art to provide a longer slot and a larger internal cavity capable of accepting two T-fasteners with a connecting tether extending through an adjacent slot to the device of Strecker other than impermissible hindsight

Therefore, Strecker in view of Hlavka and Moss does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

“the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (2007).” (MPEP 2141, II.)

For at least the reasons discussed above, it is believed that the combination of Strecker, Hlavka, and Moss fails to provide all elements of the invention, such as a fixation component slideably disposed in each of the delivery channels, each such fixation component comprising a first fixation member, a second fixation member, and a tether connecting the first and second fixation members through a longitudinal slot therebetween. Further, the Examiner has failed to provide the necessary motivation for one of ordinary skill in the art to make the combination and the rejection fails at least two portions of the *Graham* inquiry. Accordingly, Applicants respectfully request that the rejections of independent claims 1 and 16 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

For this reason, as well as others, it is believed that claims 2, 3, 5-9, 17, 19, and 20, which depend from nonobvious claims 1 and 16 respectively, are nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 10-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker in view of Miller (WO 02/17797), Hlavka, and Moss. After careful review, Applicant must respectfully traverse this rejection.

In addition to the multiple deficiencies of Strecker in view of Hlavka and Moss as acknowledged and discussed above, the Examiner has further acknowledged that Strecker does not disclose “an inner sheath, a releasable fixation member and an expandable member at the distal end of the sheath” as found in claim 10. Miller has been advanced as teaching the missing “inner sheath” in the form of element 210 of Fig. 12; as teaching “a releasable fixation member releasably fixing the vascular graft to a distal end of the inner sheath”, identified as element 235 of Fig. 16; “an expandable member expandable from a contracted position closely proximate an exterior of the delivery sheath to an expanded position urging the vascular graft against the wall of the body cavity (Fig. 15, Item 210)”; and “the expandable member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery system in the deployment position (210)”.

Instead, element 210 of Miller, said by the Examiner variously to be an “inner sheath” and/or “an expandable member” is identified by Miller simply as a balloon catheter. Element 235 of Fig. 16 appears to have been identified as a “releasable fixation member” by the Examiner; however Miller identifies element 235 as “an outer endovascular graft delivery sheath”. This latter usage is consistent with the common usage of the term “sheath” in the medical device art:

sheath: a tubular case or envelope. (Dorland's Illustrated Medical Dictionary) but not with the more complex multi-wall structure of a balloon catheter such as element 210 of Miller. Miller is said to rely upon an operation in which “balloon catheter 210 is inflated so as to ensure full expansion of graft 225 and stent 230”. The Examiner proposes that the balloon catheter 210 of Miller, serving as the inner sheath of the pending claim in a modification of Strecker “would restrain the delivery members, arranged generally radially about an exterior surface of the inner sheath (claim 10), until deployment. It is unclear how the balloon catheter 210 would restrain the expansion of delivery members to which it does not appear to be attached. The delivery tubes 215 of Miller are preformed to return to a given angle relative to guide wire 205 and so would be expected to extend their piercing (not blunt) points through the vessel wall. In fact they appear to do so while the non-restraining balloon catheter 210 is in position as illustrated in Figs.12, 13, 19, 20, and 21. For at least the reason that the balloon catheter 210 appears to be incapable of providing the restraint which the Examiner proposes as the

motivation for one of ordinary skill in the art to incorporate the balloon catheter of the Miller reference and the acknowledged failure of Strecker, Hlavka, and Moss to provide this and other elements of claim 10 as discussed above, it is believed that Strecker in view of Miller, Hlavka and Moss does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and further that one of ordinary skill in the art would not be motivated to combine the elements in the manner proposed. Accordingly the combination of references does not appear to render claim 10 obvious and Applicants respectfully request that the rejection be withdrawn.

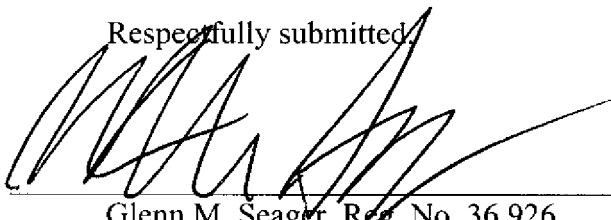
Since claim 10 has been shown to be nonobvious under §103, it is believed that claims 11-15 are also nonobvious and Applicants respectfully request that the rejection be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



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